REMARKS

The Official Action dated August 21, 2007 has been carefully considered. It is believed that the present Amendment places this application in condition for allowance, and reconsideration and an early allowance are respectfully requested.

By the present amendment, nonelected claims 1-8 and 15-17 are cancelled. Claims 9-14 and 18-20 are pending.

In the Official Action, claim 9 was rejected under 35 U.S.C. §103 as being obvious and unpatentable over the Gissmann et al U.S. Patent No. 6,228,368 in view of Goldsborough et al, GenBank Accession No. J04353, Seedorf et al, *EMBO J.* (1987), Sastre-Garau et al, *J. Gen. Virol.* (2000), Sastre-Garau et al, GenBank Accession No. AJ242956, Marich et al, *Virology* (1992), Lorincz, GenBank Accession No. M74117, and Buck et al, *Biotechniques* (1999). The Examiner asserted that Gissmann et al teach a sequence that can be used for designing primers of SEQ ID NOS: 1 and 2 and the probe of SEQ ID NO: 21 for detection and quantification of HPV 16, and the Examiner relied on the secondary references as teaching additional sequences that can be used for designing primers of SEQ ID NOS: 3-10 and the probes of SEQ ID NOS: 22-25 for HPV 18, 31 and 45. The Examiner asserted that it would have been obvious to utilize the sequences taught by the cited references in order to design amplification primers and probes for a kit to detect and quantitate HPV in a type-specific manner. The Examiner further asserted that since the claimed primers simply represent structural homologues of the oligonucleotides taught by the cited references, which are 100% derived from sequences especially suggested by the prior art as useful for primers for detection and quantification of HPV, the claimed combination of primers is obvious. The Examiner relied on Buck et al as providing evidence of the equivalence of primers and asserted that Buck et al provide direct evidence that all primers would be expected to

function, whereby one of ordinary skill in the art would have a reasonable expectation of success.

Claims 10 and 11 were rejected under 35 U.S.C. §103 over the aforementioned references and in further view of Yoo et al, *Genomics* (1993), which the Examiner asserted as teaching a sequence that can be used for designing primers of SEQ ID NOS: 19 and 20 and the probe of SEQ ID NO: 30. Claims 12 and 14 were rejected under 35 U.S.C. §103 over the aforementioned references and in further view of Swan et al, *J. Clin. Microbio.* (1997), which the Examiner asserted as teaching type-specific fluorogenic probe assays for detection and quantification of HPV. Finally, claims 13 and 18-20 were rejected under 35 U.S.C. §103 over the aforementioned references and in further view of Swan, the Examiner again relying on Swan's fluorogenic probe assays.

These rejections are traversed and reconsideration is respectfully requested. None of the combinations of cited references teach or suggest a kit as defined by any of claims 9-14 and 18-20, or the improvements provided thereby for detection and quantification of human papillomavirus (HPV).

More particularly, as defined by independent claim 9, the present invention is directed to a kit for detection and quantification of human papillomavirus (HPV). The kit comprises a) the amplification primers SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5/SEQ ID NO:6, SEQ ID NO:7 and SEQ ID NO:8, and the probes SEQ ID NO:21, SEQ ID NO:22 and SEQ ID NO:23/SEQ ID NO:24, for HPV 16, 31, 18, 45; and optionally b) the amplification primers SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13/SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16 and SEQ ID NO:17/SEQ ID NO:18 and the probes SEQ ID NO:25, SEQ ID NO:26 and SEQ ID NO:27/SEQ ID NO:28/SEQ ID NO:29 for HPV 33, 35, 39, 52, and 58.

As described in the present specification, for example at page 2, beginning at line 24, the kit of the present invention has the advantage of detecting and quantifying the HPV types most commonly detected in cervical tumors, while, importantly, minimizing the number of parallel reactions performed for each sample, making the system suitable for use in routine screening of cervical swab samples. Further, as described in the specification, for example at page 3, line 8, the probes are selected so as not to compete during amplification-reaction and detection. Particularly, the Examiner's attention is directed to the present specification at page 10, line 14, which discloses that the primers and probes in the kit of claim 9 are selected and combined to optimize the ability for balanced, co-amplification of different HPV types in a mixed sample and to avoid hindrances to an efficient PCR. As described in detail at pages 17-20 of the present application, the kit of claim 9 makes it possible to analyze multiple types of HPV, or groups of HPV, in one reaction vessel by providing the claimed combination of primers which do not compete during amplification. The kit of the invention therefore provides a significant advantage in the ability to quantify individual HPV types in mixed infections.

Each of the references cited in the rejection respectively discloses a specific primer or probe or a combination thereof. However, none of these references teach the combination of primers of SEQ ID NOS: 1-8 and probes of SEQ ID NOS: 21-24 as required by claim 9, or, importantly, that such a combination of primers and probes may be employed in a single kit to analyze multiple types of HPV, or groups of HPV, in one reaction vessel, without competition among the primers during amplification. In fact, Buck et al teach away from such a combination and demonstrate the nonobviousness of the presently claimed kit as Buck et teach that every primer would be suitable. However, Buck et al are only interested in amplification of a test nucleic acid. On the other hand, the kit of the present invention allows a primer pair to amplify a specific nucleic acid while, at the same time, not amplifying a very

similar nucleic acid. There is no teaching, suggestion, or motivation in any of the cited references to provide the specific combination of primers recited in claim 9, particularly to obtain this functionality.

As recently noted by the Supreme Court, in determining patentability under 35 U.S.C. §103, it is necessary to determine whether there was an apparent reason to combine the known elements in the fashion of the claim at issue, *KSR International Co. v. Teleflex, Inc.*, 127 F.Ct. 1727, 1740-41 (2007). None of the cited references provide any apparent reason to combine their teachings in a single kit as presently claimed, particularly with the ability to analyze multiple types of HPV, or groups of HPV, in one reaction vessel, without competition among the primers during amplification. Accordingly, the kits defined by claim 9, and claims 10-14 and 18-20 dependent thereon, are nonobvious over and patentably distinguishable from the cited combinations of references, and the rejections under 35 U.S.C. §103 have been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the Official Action and places the present application in condition for allowance. Reconsideration and an early allowance are requested. In the event that there are any outstanding issues in the present application, the Examiner is encouraged to contact the undersigned to discuss the same in order to further expedite prosecution.

Please charge any fees required in connection with the present communication, or credit any overpayment, to Deposit Account No. 04-1133.

Respectfully submitted,

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